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10/700,018

11/03/2003

Paul M. Lizardi

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ATLANTA, GA 30309-3915

EXAMINER

TUNG, JOYCE

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 05/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/700,018

Applicant(s)

LIZARDI, PAUL M.

Examiner

Joyce Tung

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1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 11/3/03.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 32 and 34-50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 32 and 35-38 is/are allowed.
- 6) ☒ Claim(s) 34 and 39-50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 11/03/03.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

The preliminary amendment filed 11/3/03 has been entered. Claims 32, and 34-50 are pending.

#### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 34, and 39-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Hartley (5,043,272, issued August 27, 1991).

Hartley et al. disclose a kit for amplifying a nucleic acid sequence including primers having random nucleotide sequences and polymerase possessing strand displacement activity (see column 4, lines 43-68 and column 8, lines 35-36). The sample is from human or other animal source (See column 3, lines 6-21). The primer is 5-50 bases fragment (See column 6, lines 59-62). The constant portion of the primer has the same nucleotide sequence (See column 12, lines 16-22). Thus, the teachings of Hartley et al. anticipate the limitations of the claims.

3. (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 47-49 are rejected under 35 U.S.C. 102(e) as being anticipated by McCaslin et al. (5,614,390, issued March 25, 1997).

McCaslin et al. disclose a kit to amplify a target nucleic acid using SDA (column 16, claim 23). The strand displacement DNA polymerase is Bst polymerase (See column 9, lines 14-

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15). The set of primers has 3 or more primers (See column 4, lines 49-67 and column 5, lines 1-20). Thus, the teachings of McCaslin et al. anticipate the limitations of the claims.

5. Claim 47 is rejected under 35 U.S.C. 102(e) as being anticipated by Walker et al. (5,736,365, issued April 7, 1998).

Walker et al. disclose a kit used to pack the primer or the probes for performing the assay (See column 10, lines 54-57). The primer set has 3 or more primers (an amplification primer, an adapter primer and a bumper primer) (See column 4, lines 48-67, column 5, lines 18). The polymerase has a strand displacement factor (See column 11, lines 29-30). Thus, the teachings of Walker et al. anticipate the limitations of the claims.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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7. Claims 46 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hartley (5,043,272, issued August 27, 1991) as applied to claims 34 and 39-45 or over McCaslin et al. (5,614,390, issued March 25, 1997) as applied to claims 47-49 or over Walker et al. (5,736,365, issued April 7, 1998) as applied to claim 47 above, and further in view of Blanco et al. (Journal of Biological Chemistry, 1989, Vol. 264(15), pg. 8935-40).

None of the references above discloses that the kit contains phage vphi 29 DNA polymerase for strand displacement.

Blanco et al. disclose that phage vphi 29 DNA polymerase is highly processive in the absence of any accessory protein and is able to produce strand displacement coupled to the polymerization process (See the Abstract).

One of ordinary skill in the art would have been motivated to include phage vphi 29 DNA polymerase in the kit for amplifying a target nucleic acid as claimed because of the benefit of using the polymerase. It would have been prima facie obvious to include phage vphi 29 DNA polymerase in the kit for performing the amplification of the target nucleic acid.

***Allowable Subject Matter***

8. Claims 32 and 35-38 are allowed.

9. The following is a statement of reasons for the indication of allowable subject matter:

Concerning claims 32 and 35-38, no prior art has been found teaching <sup>of</sup> and suggest<sup>ing</sup> ~~the~~ the kit comprising a set of primers wherein the set of primers comprises a right set of primers and a left set of primers, wherein the right set of primers has 4 or more primers and the left set of primers has 4 or more primers, wherein the right set of primers is all complementary to the first strand of a target sequence and each complementary to a different portion of the right hybridization target

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of the first strand of the target sequence and the left set of primers is all complementary to the second strand of the target sequence and each complementary to a different portion of the left hybridization target of the second strand of the target sequence.

The closest prior art is the reference of Walker et al. (5,736,365, issued April 7, 1998). Walker et al. disclose a kit used to pack the primer or the probes for performing the assay (See column 10, lines 54-57). The primer set has 3 or more primers (an amplification primer, an adapter primer and an bumper primer) on a right hybridization target and a left hybridization target (See column 4, lines 48-67, column 5, lines 18). Walker et al. do not disclose that the set of primers has a right set of primers and a left set of primers, wherein the right set of primers has 4 or more primers and the left set of primers has 4 or more primers.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (571) 272-0790. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Joyce Tung *JT*  
May 11, 2006

*Kenneth R. Horlick*  
KENNETH R. HORLICK, PH.D.  
PRIMARY EXAMINER

*5/11/06*